



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#27  
CC  
6-28-01

Applicant(s): Boyle et al.

Group Art Unit No.: 1632

Serial No.: 08/974,186

Examiner: Weitach, J.

Filed: November 18, 1997

Date "Notice of Allowance and Base Issue  
Fee Due" was mailed: February 21, 2001

For: OSTEOPROTEGERIN

Docket No.: A-378D5C

Issue Batch No.: C32

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

As provided in 37 CFR 1.104(e), Applicants comment herewith on the Reasons for Allowance set forth in the Notice of Allowability dated February 21, 2001.

The Examiner has indicated in his Reasons for Allowance that the Declaration of Jackie Z. Sheng and the specification teach that amino acids 22-180 are the essential portion of the encoded osteoprotegerin (OPG) polypeptide.

Applicants point out that the Declaration showed expression of an OPG fusion polypeptide from DNA encoding amino acids 1-201 of OPG fused to a human IgG1 $\gamma$ 1 polypeptide. Upon expression, the resulting OPG fusion polypeptide comprised amino acids 22-201 of OPG fused to a human IgG1 $\gamma$ 1 polypeptide. This fusion polypeptide was shown to increase bone mineral density in ovariectomized mice. The declaration did not show results from OPG polypeptides shorter than amino acids 22-201.

The specification of U.S. Serial No. 08/974,186 discloses OPG polypeptides having deletions or carboxy terminal truncations of part or all of amino acids 180-401 including OPG having residues 22-180. (See page 15, lines 5 - 16 of the specification.) An assay for the biological activity of OPG residues 22-180 is not disclosed in the '186 specification; however, the specification teaches OPG polypeptides longer than residues 22-180. As shown in the declaration, OPG of residues 22-201 has activity of increasing bone mineral density.

Applicants' comments as set forth herein are solely for the purpose of clarifying the record and are not considered material to the Examiner's decision to allow Claims 49 and 51-69 or to the reasons

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

May 21, 2001

Date

*D. Dillan*  
Signature

02.01



PATENT APPLICATION

for allowance of said claims. Applicants' comments are not to be construed as limiting the scope of any subject matter contained in the specification or claims of this or any other application related by priority.

Respectfully submitted,

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